RESOLVE
The National Infertility Association since 1974
Member of the International Federation of Infertility Patient Associations

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June 30, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 97N-484S

To Whom it May Concern:

We are writing to you with comments on the proposed rule "Suitability Determination for Donors of Human Cellular and Tissue-Based Products." RESOLVE: The National Infertility Association represents women and men experiencing infertility and provides a voice for their concerns and needs. We are commenting on the portions of the proposed rule that relate to infertility treatments.

RESOLVE applauds the FDA's analysis of the issues and its efforts to diminish the likelihood of transmitting diseases through the donation of cellular and tissue-based products. The FDA's paramount concern is for the safety of consumers. Those who undergo infertility treatments want to know that precautions are taken to protect the health and best interests of patients and of any resulting children.

Following are comments on specific aspects of the proposed regulations:

RESOLVE supports the recommendation that records regarding gamete donation be kept for 10 years.

RESOLVE supports requiring all sperm banks to comply with the proposed screening and testing regulations.

RESOLVE is concerned about the proposal which would allow patients and physicians to decide whether to use donated gametes from a directed donor who is found to be unsuitable. It is essential that patients be fully informed, and written contracts indicating the possible risks to recipient and baby be signed, so that there is a complete understanding of the risks involved before deciding whether to use that donor.

The proposed regulations mention leukocyte-rich cells and tissue that need to be tested for additional evidence of disease. Oocytes and embryos are not leukocyte-rich. This should be clarified in the mention of reproductive cells and tissue that are leukocyte-rich.

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The proposed regulations state that testing for chlamydia and gonorrhea does not need to take place when oocytes are retrieved through laparoscopy. Today, most oocytes are retrieved through vaginal ultrasound techniques, so the exception to testing for those STDs would not apply in most cases.

Cellular material other than from the patient is sometimes used in co-culture for IVF, and RESOLVE questions why this is not also addressed in these regulations.

The proposed regulations require that when donated oocytes are used to create embryos, the embryos should be frozen for 6 months, when the donor can be retested, before they are transferred. RESOLVE would like to know what kind of evidence there is to justify this recommendation. If this recommendation is based on evidence of a risk of disease transmission, then RESOLVE supports the requirement to wait 6 months, in order to reduce the chances of an infectious disease being passed on to the patients or the children.

The proposed regulations would appear to foreclose the donation of embryos created and frozen before the effective date of the regulations, if the donors had not been screened at the time the embryos were created. Since there are an estimated 150,000 frozen embryos in the U.S., created primarily by couples undergoing infertility treatment, the regulations would seem to limit their options to destruction of unused embryos, donation for research or indefinite storage. In the absence of clear evidence that embryo donation poses risks of disease transmission, RESOLVE is concerned about virtually eliminating embryo donation as an option.

Throughout the report, concerns are raised regarding the lower success rates when frozen embryos are used. The success rate for frozen embryo transfers in the latest SART report, which looked at cycles initiated in 1997, was 18.6%. The success rate for fresh cycles was 29.7%. Hopefully, these statistics will improve in current and future cycles. In the absence of evidence of potential disease transmission through non-leukocyte rich cells (eggs), and given the lower success rate for frozen embryo transfers, RESOLVE would not support the elimination of the fresh donor egg option for family building.

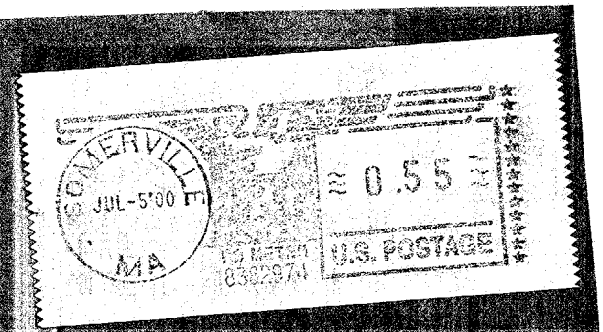
RESOLVE looks forward to a time when donated oocytes can be frozen for later use, which would ease some of the potential problems that may arise under the proposed regulations regarding freezing of embryos.

Thank you for your efforts to increase safety and quality of care for infertility patients. Please contact us if we can be of further assistance.

Sincerely,

Margaret R. Hollister

Margaret R. Hollister, JD
Acting Executive Director



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